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Attorneys for Plaintiff Shire LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHIRE LLC,	)	
	)	
Plaintiff,	)	Civil Action No. _____
	)	
v.	)	
	)	
COREPHARMA, LLC,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Shire LLC ("Shire" or "Plaintiff"), by its undersigned attorneys, brings this action against Defendant CorePharma, LLC ("CorePharma" or "Defendant"), and hereby alleges as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 206304 to the United States Food and Drug Administration ("FDA"). Through this ANDA, Defendant seeks approval to market generic versions of the pharmaceutical product ADDERALL XR® prior to the expiration of United States Reissued Patent Nos. RE42,096 ("the '096 Patent") and RE41,148 ("the '148 Patent"). Shire seeks injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

PARTIES

2. Plaintiff Shire LLC is a limited liability company organized and existing under the laws of the State of Kentucky and has its principal place of business at 9200 Brookfield Ct., Suite 108, Florence, Kentucky 41042.

3. On information and belief, Defendant CorePharma, LLC is a limited liability company organized and existing under the laws of the State of New Jersey and has a principal place of business at 215 Wood Avenue, Middlesex, New Jersey 08846.

JURISDICTION AND VENUE

4. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '096 Patent and the '148 Patent. This Court has jurisdiction over the subject matter of this action pursuant to 28

U.S.C. §§ 1331 and 1338. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

5. On information and belief, this Court has personal jurisdiction over Defendant CorePharma, LLC because, *inter alia*, the company is incorporated in the State of New Jersey and maintains its principal place of business in New Jersey. On further information and belief, Defendant also maintains pharmaceutical manufacturing facilities in New Jersey and distributes numerous drug products from these New Jersey facilities.

SHIRE'S PATENTS AND APPROVED ADDERALL XR® DRUG PRODUCT

6. Shire, through a corporate affiliate, makes and sells ADDERALL XR®, a widely used drug product that helps control the symptoms of Attention Deficit Hyperactivity Disorder ("ADHD"). ADHD is a condition that makes it difficult for adults and children to focus their attention, control their actions, and remain still.

7. ADDERALL XR® is a once-daily product that contains dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, and amphetamine sulfate. It is marketed in six dosage strengths: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg. One or more claims of the asserted '096 and '148 Patents encompass ADDERALL XR®.

8. The '096 Patent, entitled "Oral Pulsed Dose Drug Delivery System," is a reissue of U.S. Patent. No. 6,322,819 ("the '819 Patent"), which issued on November 27, 2001. A true and correct copy of the '096 Patent is attached as Exhibit A. The '096 Patent discloses and claims, *inter alia*, a pharmaceutical composition for delivery of one or more pharmaceutically active amphetamine salts. Plaintiff Shire LLC owns the '096 Patent.

9. The '148 Patent, entitled "Oral Pulsed Dose Drug Delivery System," is a reissue of U.S. Patent No. 6,605,300 ("the '300 Patent"), which issued on August 12, 2003. A true and correct copy of the '148 Patent is attached as Exhibit B. The '148 Patent discloses and claims, *inter alia*, a pharmaceutical preparation for the delivery of mixed amphetamine salts. Plaintiff Shire LLC owns the '148 Patent.

10. Shire Development LLC, an affiliate of Shire, holds New Drug Application ("NDA") No. 21-303, under which FDA approved the marketing of ADDERALL XR® for the treatment of ADHD. FDA has listed the '096, '148, '819, and '300 Patents in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for NDA No. 21-303 because those patents cover ADDERALL XR®.

DEFENDANT'S ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

11. On information and belief, Defendant submitted or caused to be submitted ANDA No. 206304 ("CorePharma ANDA") to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of the products described therein ("the ANDA Products") as purported generic versions of ADDERALL XR® prior to the expiration of the '096 and '148 Patents.

12. On information and belief, on or about August 1, 2014, Defendant's counsel sent Shire a Notice of Paragraph IV Certification ("Notice Letter"). The Notice Letter represented that Defendant had submitted to FDA the CorePharma ANDA and a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the CorePharma ANDA before the expiration of the patents listed in the Orange Book for NDA No. 21-303.

Hence, Defendant's purpose in submitting the CorePharma ANDA is to manufacture and market the ANDA Products before the expiration of the '096 and the '148 Patents. The Notice Letter also stated that the Paragraph IV Certification alleges that the '096 and the '148 Patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

13. On information and belief, Defendant has assisted with and participated in the preparation and submission of the CorePharma ANDA, has provided material support to the preparation and submission of the CorePharma ANDA, and intends to support the further prosecution of the CorePharma ANDA.

14. On information and belief, if FDA approves the CorePharma ANDA, Defendant will manufacture, offer for sale, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States.

15. On information and belief, if FDA approves the CorePharma ANDA, Defendant will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Products in the United States.

16. Shire brings this action pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of receipt of the Notice Letter. *See* 21 U.S.C. § 355(c)(3)(C).

COUNT I: CLAIM FOR INFRINGEMENT OF THE '096 PATENT

17. Shire states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

18. On information and belief, Defendant has submitted or caused the submission of the CorePharma ANDA to FDA, and continues to seek FDA approval of the CorePharma ANDA.

19. Defendant has infringed the '096 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the CorePharma ANDA with a Paragraph IV Certification and seeking FDA approval of the CorePharma ANDA prior to the expiration of the '096 Patent.

20. Defendant's commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '096 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206304, Defendant will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '096 Patent.

21. On information and belief, upon FDA approval of ANDA No. 206304, Defendant will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Defendant will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for administering the ANDA Products. Accordingly, Defendant will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '096 Patent. In addition, on information and belief, Defendant will encourage acts of direct infringement with knowledge of the '096 Patent and knowledge that it is encouraging infringement.

22. Defendant had actual and constructive notice of the '096 Patent prior to filing the CorePharma ANDA with FDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '096 Patent would constitute an act of infringement of the '096 Patent. Defendant has no reasonable basis for asserting that the

commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '096 Patent. In addition, Defendant filed the CorePharma ANDA without adequate justification for asserting the '096 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendant's conduct in certifying invalidity and non-infringement with respect to the '096 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

23. Shire will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing and contributing to the infringement of the '096 Patent. Shire does not have an adequate remedy at law, and considering the balance of hardships between Shire and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II: CLAIM FOR INFRINGEMENT OF THE '148 PATENT

24. Shire states, realleges, and incorporates by reference the foregoing paragraphs as if fully set forth herein.

25. On information and belief, Defendant has submitted or caused the submission of the CorePharma ANDA to FDA, and continues to seek FDA approval of the CorePharma ANDA.

26. Defendant has infringed the '148 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the CorePharma ANDA with a Paragraph IV Certification and seeking FDA approval of the CorePharma ANDA prior to the expiration of the '148 Patent.

27. Defendant's commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products would directly

infringe, and would actively induce and contribute to infringement of the '148 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206304, Defendant will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '148 Patent.

28. On information and belief, upon FDA approval of ANDA No. 206304, Defendant will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Defendant will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for administering the ANDA Products. Accordingly, Defendant will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '148 Patent. In addition, on information and belief, Defendant will encourage acts of direct infringement with knowledge of the '148 Patent and knowledge that it is encouraging infringement.

29. Defendant had actual and constructive notice of the '148 Patent prior to filing the CorePharma ANDA with FDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '148 Patent would constitute an act of infringement of the '148 Patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '148 Patent. In addition, Defendant filed the CorePharma ANDA without adequate justification for asserting the '148 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products.

Defendant's conduct in certifying invalidity and non-infringement with respect to the '148 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

30. Shire will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing and contributing to the infringement of the '148 Patent. Shire does not have an adequate remedy at law, and considering the balance of hardships between Shire and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Shire respectfully requests the following relief:

(a) The entry of judgment, in favor of Plaintiff and against Defendant, that Defendant, through its submission of ANDA No. 206304 to FDA seeking to market the ANDA Products, has infringed the '096 and '148 Patents under 35 U.S.C. § 271(e)(2)(A);

(b) The entry of judgment, in favor of Plaintiff and against Defendant, declaring that the making, using, selling, offering to sell, or importing of the products for which approval is sought in the CorePharma ANDA, or inducing or contributing to such conduct, would constitute infringement of the '096 and '148 Patents by Defendant pursuant to 35 U.S.C. §§ 271(a), (b), (c) and (g);

(c) The entry of a permanent injunction, enjoining Defendant and its officers, directors, agents, servants, employees, parents, subsidiaries, affiliate companies, other related business entities, and all other persons and entities acting in concert, participation, or in privity with Defendant, and their successors or assigns, from infringing, inducing infringement of, and contributing to the infringement of any claims of the '096 and '148 Patents by making, using, selling, offering for sale, or importing the ANDA Products in the United States;

(d) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 206304 shall be a date that is not earlier than the last expiration date of the '096 and '148 Patents, or any later expiration of exclusivity for the patents, including any extensions or regulatory exclusivities;

(e) The entry of judgment declaring that Defendant's acts render this case an exceptional case, and awarding Plaintiff its attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(f) An award to Plaintiff of its costs and expenses in this action; and

(g) Such other and further relief the Court deems just and proper.

DATED: September 12, 2014

Respectfully submitted,

/s/ Sherilyn Pastor
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Attorneys for Plaintiff Shire LLC

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Plaintiff, by its undersigned counsel, hereby certifies pursuant to L. Civ. R. 11.2 that the matters in controversy in the instant action are not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 12, 2014

/s/ Sherilyn Pastor
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